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Environmental Protection Agency

Federal Radiation Protection Guidance for Occupational Exposures

[RH-FRL 1722-5]

Federal Radiation Protection Guidance for Occupational Exposures; Proposed Recommendations, Request for Written Comments, and Public Hearings

AGENCY: U.S. Environmental Protection Agency.

ACTION: Proposed recommendations for radiation protection of workers.

SUMMARY: We are proposing to make recommendations to the President for new guidance to Federal agencies for the protection of workers exposed to ionizing radiation. These proposals are based on a review of existing guidance in the light of scientific knowledge of radiation risks and of experience in the control of occupational exposure. The proposed recommendations include both qualitative guidance on radiation protection and numerical guides for maximum allowed dose equivalents (RPG's[1]). The most significant changes proposed are (a) that a graded set of minimum radiation protection requirements be introduced in three levels; (b) that the RPG for maximum whole-body dose equivalent be reduced from three rem [2] per quarter to five rem per year, and that regulatory agencies establish lower limits for specific types of work situations; (c) that limitation of internal doses [3] take into account the sum of the risks to all organs, rather than continue to be based only on the most significantly exposed organ; (d) that the RPGs for the whole body apply to the appropriately weighted sum of the doses from both internal and external exposures; and (e) that the dose to the embryo and the fetus be limited through one of several alternative recommendations.

We welcome written comments on these proposals and will hold public hearings as discussed below. We will carefully consider all oral and written comments in preparing our final recommendations to the President.

DATES: 1. All written comments in response to this notice must be received by us by April 24, 1981, in order to be used.

2. Public hearings will be held at the following locations, beginning no earlier than 60 days following publication of this notice: Washington, D.C., Chicago, Illinois, San Francisco, California, Houston, Texas. We will publish the times and addresses for these hearings shortly.

3. Instructions of interest to those who wish to appear at the public hearings are given below under the heading "Public Hearings."

ADDITIONAL INFORMATION: We will be happy to send a copy of a background report which provides additional information on these proposed recommendations to anyone requesting it. Please send requests to Mr. Luis F. Garcia at the address below. This report is also available for inspection and copying at EPA's Central Docket Section and ten Regional Offices (addresses below).

ADDRESSES: Written comments should be addressed to the Director, Criteria and Standards Division (ANR-460), U.S. Environmental Protection Agency, Washington, D.C. 20460, Attention: Docket No. A-79-46. These comments and the public hearing record will be filed under the above docket number and will be available for inspection and copying at the U.S. Environmental Protection Agency's Central Docket Section, Room 2903B, Mall 401 M Street, S.W., Washington, D.C. 20460, and at the Agency's library in each of its ten regional offices: *Region I:* JFK Building, Room 2100-B; Boston, Massachusetts 02203 (Tel. 617-223-5791); *Region II:* 26 Federal Plaza, Room 1002, New York, New York 10278 (Tel. 212-264-2881); *Region III:* Curtis Building, 6th & Walnut Streets, Philadelphia, Pennsylvania 19106 (Tel. 215-597-0580); *Region IV:* 345 Courtland Street, N.E., Atlanta, Georgia 30365 (Tel. 404-881-4216); *Region V:* 230 South Dearborn Street, Room 1417, Chicago, Illinois 60604 (Tel. 312-353-2022); *Region VI:* First International Building, 1201 Elm Street, 28th Floor, Dallas, Texas 75270 (Tel. 214-767-7341); *Region VII:* 324 East 11th Street, Kansas City, Missouri 64106 (Tel. 816-374-3497); *Region VIII:* Radiation Program Office (in lieu of library), 1860 Lincoln Street, Second Floor, Denver, Colorado 80203 (Tel. 303-837-2221); *Region IX:* 215 Fremont Street, 6th Floor, San Francisco, California 94105 (Tel. 415-556-1841: *Region X:* 1200 Sixth Avenue, 12th Floor, Seattle, Washington 98101 (Tel. 206-442-1289).

FOR FURTHER INFORMATION CONTACT: Contact Mr. Luis F. Garcia, U.S. Environmental Protection Agency (ANR-460), Washington, D.C. 20460 (Telephone 703-557-8224), about these proposed recommendations or the public hearings.

SUPPLEMENTARY INFORMATION:

Statutory Authority

The Administrator of the Environmental Protection Agency (EPA) is charged under Executive Order 10831, Reorganization Plan No. 3 of 1970, and Public Law 86-373 to "* * * advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States." This guidance has historically taken the form of qualitative and quantitative "Radiation Protection Guidance." The recommendations we propose here would replace those portions of existing Federal guidance that apply to radiation protection of workers, which were adopted in 1960 (25 FR 4402).

Previous Actions by EPA

We began this review of the 1960 radiation protection guidance for workers in 1974. The most recent notice of this activity listed the principal issues being addressed and announced our intent to hold public hearings on proposed recommendations (44 FR 53785, Sept. 17, 1979).

We have sponsored two major studies in support of this program. First, the Committee on the Biological Effects of Ionizing Radiations, National Academy of Sciences—National Research Council, has reviewed the scientific data on the health risks of low level ionizing radiation developed since its 1972 report. Second, we have carried out a study of occupational radiation exposures and published our findings in a report entitled: "Occupational Exposure to Ionizing Radiation in the United States: A Comprehensive Summary for the Year 1975." We have also considered recent recommendations of the National Council on Radiation Proctection and Measurements.

In developing these proposals, we have also consulted with the technical staffs of the Federal agencies that regulate or influence the regulation of occupational exposure, and will continue this consultation in developing final recommendations. These agencies are the Occupational Safety and Health Administration, the Nuclear Regulatory Commission, the Mine Safety and Health Administration, the Department of Defense, the Department of Energy, the Department of Transportation, the Food and Drug Administration, the National Aeronautics and Space Administration, the National Institute for Occupational Safety and Health, and

[1] Radiation Protection Guides.

[2] A *rad* is a unit of measure for dose, i.e., the amount of ionizing radiation energy absorbed per unit weight of tissue. Thus, the same energy absorbed by twice as much tissue gives only one-half the number of rads. The *rem*, a unit for dose equivalent, is a rad multiplied by factors which describe how damaging the type of radiation is.

[3] In this notice we henceforth use "dose" to mean "dose equivalent."

the National Bureau of Standards. These agencies, which have not formally endorsed these recommendations, will formally review final proposals when they are developed following public review.

Issues Addressed

The principal issues we addressed in formulating these recommendations were identified in the advance notice cited above. They were:

1. Are the doses currently received by workers and the maximum doses permitted under existing guidance adequately low? In this regard, a) how adequate is the basis used for estimating risks to health from radiation exposure, and b) what are the appropriate bases for judging maximum individual and collective radiation doses in the work force and the tradeoffs between these two indices of the health impact of occupational exposure?

2. Should the same guides apply to all categories of workers (e.g., dental workers, nuclear medicine technicians, nuclear maintenance personnel, industrial radiographers)? Should specific guides be developed for pregnant women, female workers who could bear children, and/or men?

3. On what time basis should the guides be expressed? Quarterly? Annual? Should the lifetime occupational dose be limited? Should the age of the worker be a factor?

4. Should the guidance reflect or cover medical, accidental, and/or emergency exposures?

5. Is existing guidance for situations that involve exposure of less than the whole body adequate? In this respect, a) what organs and parts of the body should have designated limits, and b) on what basis should guidance be expressed for exposure of more than one organ or portion of the body?

6. How should the radiation protection principles requiring a) justification of any exposure, and b) reduction of the dose from justified exposures to the lowest practicable or as low as is reasonably achievable level be applied to exposure of workers? Should the concept of lowest feasible level be applied to exposure of workers?

7. What, if any, relationship should be maintained between permissible levels of risk to health from radiation exposure and other regulated hazards of disease or accidents?

Additional issues suggested since publication of the advance notice include:

8. Should the guidance include numerical values for the factors (called "quality" and "modifying" factors) used to convert dose (measured in rads) to dose equivalent (measured in rem)? If so, should this be developed now or issued later as supplementary guidance?

9. What guidance should apply to workers who do not use radiation sources, but who are exposed to radiation due to the activities of workers under the control of other employers?

10. Are there situations that may require doses higher than normally permitted? Should we provide special guidance for them?

Many of these issues are addressed below. However, for a more complete and extensive discussion please refer to the background report cited above under the heading "Additional Information."

Risks From Occupational Exposure

There are three kinds of risks from the low levels of ionizing radiation characteristic of occupational exposures. The most important of these is cancer, which is fatal at least half the time. Another risk is the induction of hereditary effects in descendants of exposed persons. The severity of these effects ranges from fatal to inconsequential. We assume that at low levels of exposure the risk of cancer and hereditary effects is in proportion to the dose received, and that the severity of any induced effect is independent of the dose level. That is, while the probability of a given type of cancer occurring increases with dose, such a cancer induced at one dose is equally as debilitating as that same type of cancer induced at another dose. Thus, for these effects we assume that there is no completely risk-free level of radiation exposure.

The third type of risk includes a variety of other effects on workers and on the children of women exposed during pregnancy. These effects range from serious effects on children, such as mental retardation, to less serious effects on workers, such as opacification of the lens of the eye and temporary impairment of fertility. For these effects we believe the degree of damage (i.e., the severity) depends to some extent on the dose level. At the dose levels allowed by current radiation protection guides, we believe that none of the effects on workers themselves occurs to a degree sufficient to be clinically detectable. At these levels, however, effects on children exposed in utero may be serious.

The risks of effects on health from low level ionizing radiation were reviewed for EPA by the National Academy of Sciences (NAS) in reports published in 1972 and in 1980. We have used these studies and others to estimate the risks associated with the current and proposed Federal guides for limiting radiation dose. Details of these and other risk estimates we use are provided in the accompanying background report.[4]

A worker who received the largest lifetime dose allowed under present guides (5 rem per year from age 18 to assumed retirement at age 65, or 235 rem) would have a lifetime risk of about 3 to 6 in 100 of dying from radiation-induced cancer, and numerically comparable chances both of nonfatal cancer and, for male workers, of mutational effects in his descendants.[5] Risks of mutational effects from exposure of female workers are assumed to be three to four times smaller. However, in our recent national survey of exposures for the year 1975, 99% of all workers received less than half of, and only 0.15% exceeded, an annual dose of 5 rem. Based on these and other data, we believe that only a few workers involved in accidents have received close to the current maximum allowed lifetime dose.

The average worker exposed to radiation sustains only a small risk of death from radiation. The estimated average risk of death due to radiation-induced cancer is smaller, for example, than the risk of job-related accidental death in the safest of all major occupational categories, retail trades, for which the annual death rate was 60 per million workers in 1975. We estimate that the collective dose to the more than one million workers potentially exposed to radiation in their workplace for that same year will not lead to more than 15–36 premature cancer deaths. Other ways of expressing this risk are that the exposure of an average worker to radiation in 1975 represented an average lifeshortening of about two to three and a half hours, or an average increase in his chance of cancer death of about one to three in 100,000. In 1975 about one sixth of United States deaths were from cancer.

The comparative time-loss associated with nonfatal cancer is also estimated to be very small. The average time lost by

[4] Our estimated ranges of risk for cancer death are based on absolute and relative linear risk models used by the 1972 BEIR Committee and the assumption that the risk of incurring most radiogenic cancers continues throughout the lifetime of exposed persons. The 1980 BEIR report, which was just published, gives estimates based on a variety of risk models, some of which yield lower and some higher values. Based on our preliminary review, we do not believe that the differences between these values and those we have adopted here would lead to any changes in these proposals.

[5] Mutational effects here mean those hereditary effects included by the BEIR Committee in their 1972 report as serious disabilities. Examples are congenital malformations leading to premature death, hemophilia, sickle cell anemia, cystic fibrosis, diabetes, schizophrenia, and epilepsy.

U.S. workers due to all occupationally-related injuries and illnesses over a working lifetime is one month. For radiation-induced nonfatal cancers it is estimated to be about four days for a hypothetical individual receiving the largest lifetime dose allowed (235 rem), and for the average worker it is about two hours.

Limitation of Whole Body (External) Exposure

Based on these observations, risks due to occupational exposure to radiation do not appear to be unreasonably high for the average worker. They are comparable to risks of accidental death in the least hazardous occupations. However, a worker exposed to the current maximum allowed dose year after year would sustain substantial risks. The proposed radiation protection guidance contains provisions to avoid the accumulation of large lifetime doses through reduction of the maximum allowed annual dose and through specific minimum radiation protection requirements for workers in high-dose work situations. These include on-the-job radiation protection supervision for high-dose jobs, maintenance of lifetime dose records, and an admonition that exposure of workers should be managed so that their lifetime doses do not exceed 100 rem.

Existing Federal guidance permits doses up to 3 rem per quarter (or 12 rem per year), within an overall cumulative limit of 5(N–18) rem, where N is the age of the worker. This flexibility, which allows annual doses greater than 5 rem, does not permit specific tasks that require doses to individuals of more than 5 rem (since the 3 rem per quarter limit prohibits this), but it does permit the same worker to accomplish several tasks requiring doses at or near this quarterly limit in a given year. In view of the risks, it is our judgement that repeated exposures in a year at such levels should not occur, and these recommendations would eliminate this flexibility. One appropriate solution in cases where workers with specific skills are in short supply is to train additional workers, rather than to impose higher risks on a few individuals.

Because we assume that any exposure carries some risk, we believe that it is important to avoid unnecessary exposures at any exposure level. Although more than 97% of all workers in our survey received annual doses less than one rem, these same workers accumulated about half of the collective dose received by the entire work force. Many of these workers, because their doses are low compared to the limits, may receive only minimal training, supervision, and monitoring for radiation protection. Many also work in situations where there is no need for exposures to ever approach the existing or the proposed new RPGs. On the other hand, some exposures at higher doses are justified. The proposed recommendations, therefore, provide a graded system of radiation protection which would establish minimum radiation protection requirements for each of three different ranges of exposure within the basic guides for maximum allowed dose to all workers. We anticipate that maximum exposure of the vast majority of workers would be effectively limited to the lowest of these ranges (less than approximately 0.5 rem to the whole body per year) through the deterrent of requirements for increased justification, on-the-job radiation protection supervision, and monitoring in the two higher ranges. In addition, the recommendations encourage regulatory agencies to establish more restrictive regulatory limits for work situations not requiring the maximum doses allowed under the basic guides.

The proposed guidance leaves agencies considerable discretion in implementing the minimum radiation protection requirements for justification of exposure of workers in each of the various ranges. We are considering additional guidance which would recommend the establishment of more explicit requirements for the highest range (Range C). These requirements could include establishment of criteria for use of Range C, or prior application to and approval by the regulatory agency of Range C exposure (either for specific or more general job situations). We request specific comments on these and similar approaches to further restrictions on the exposure of workers at these higher levels.

We have considered both higher and lower alternatives to the proposed 5 rem/year RPG for whole-body exposure. This value is proposed because (a) it is the current internationally-accepted value, (b) there appear to be essential jobs requiring near 5 rem per year, and (c) the risks to the few workers in these jobs are not high compared to other industrial hazards. In addition, the costs for levels significantly lower (one rem/year or less) appear to be unwarranted, both in terms of increased collective dose to the entire workforce (in return for a few lower individual doses), and in terms of increased economic costs.

In 1975 the National Council on Radiation Protection and Measurements took the position that no change was required in the recommendation given by it in 1971. That recommendation is that "The maximum permissible prospective dose equivalent for whole body irradiation from all occupational sources shall be 5 rems in any one year" (NCRP Report No. 39, Jan. 15, 1971). Likewise the International Commission on Radiological Protection in 1977 recommended a basic dose-equivalent annual limit of 5 rem for whole body exposures to ionizing radiation (ICRP Publication 26, Jan. 17, 1977). In support of its recommendation the ICRP states that "The Commission believes that for the foreseeable future a valid method for judging the acceptability of the level of risk in radiation work is by comparing this risk with that for other occupations recognized as having high standards of safety, * * *." The radiation risk factors given in ICRP Publication 26 in arriving at its recommendation were reviewed by ICRP in May 1978 and no changes were made (ICRP Publication 28, 1978).

Nevertheless, these recommendations are all value judgments; there is not now compelling evidence for any particular value and it is hard to get such evidence. In judging the acceptability of the risks involved, it is necessary to identify (a) activities that cannot be performed at particular maximum dose levels, (b) skilled professionals and workers in limited supply whose numbers would be difficult to quickly increase in order to reduce average annual doses, and (c) the costs for additional workers and equipment that would be needed to meet different limits. For example, we are aware of a small number of maintenance tasks at nuclear power stations that could not be done under some limits less than 5 rem/year. There may be many more examples of professions, principally in medical areas, with limited labor pools. These include cardiologists performing catheterizations using fluoroscopy; and radiologists, neuro-radiologists, and nuclear medicine technologists with large patient loads for special procedures. Finally, studies by the Department of Energy and the nuclear power industry report that large costs and many more workers would be needed to greatly reduce the dose limits for many operations. Their projections of costs and personnel requirements increase expotentially with decreasing limits. We therefore request, in addition to comment on reduction of the current RPG of 3 rem/quarter to our proposed recommendation of 5 rem/year, comment on the above factors for reduction of the current RPG to 0.5 rem/year, 1 rem/year, and 3 rem/year.

Limitation of Partial Body Exposures

Exposure of portions of the body can occur through localized irradiation of

extremities (such as hands in glove boxes), or by breathing or swallowing radioactive materials, which then migrate to different organs of the body.

Current guidance limits such exposures through separate numerical guides for organs and for individual parts of the body that are easily exposed, such as hands and feet or lens of the eye. Some organs recognized as easily subjected to high doses or as particularly sensitive to radiation have specific guides.

These current guides are applied separately. For example, even though a worker has received the maximum allowed dose to his thyroid, he may also receive doses to his lungs, skin, or any other organ, as long as no single organ receives more than the dose specified by its guide. We assume that the risks associated with such multiple doses are additive.

An alternative approach is to limit the total risk of fatal cancer in all exposed organs. This method has been adopted by the International Commission on Radiological Protection (ICRP). It is also adopted in these recommendations, but only when it leads to a greater degree of protection than limiting the dose to critical organs. Specifically, the recommended guidance provides that (a) either the combined risk of fatal cancer from all doses to individual organs not exceed the risk permitted under the whole body guide or (b) the dose to the most significantly exposed organ not exceed its guide, whichever is more restrictive. The recommendations also provide, when workers receive both external doses from whole-body exposure and internal doses from radionuclides, that the sum of the risks of fatal cancer from external whole-body doses and those due to breathing or swallowing radioactive materials not exceed the risk of fatal cancer allowed by the whole-body guide.

The numerical weighting factors chosen to relate risks to individual organs to whole-body risk are discussed in the background report cited above. In general, they are consistent with recent determinations of risk of fatal cancer by national and international scientific bodies, such as the NAS and the ICRP.

We have chosen the limiting annual dose to most single organs to be 30 rem, rather than the internationally-adopted value of 50 rem, because we do not see a need for a value higher than any now used in this country. The risk associated with 30 rem to any of these organs is equal to or less than that of 5 rem to the whole body. Additional differences from internationally-used values for gonads, lens of eye, and hands are discussed below.

It is usually impractical to directly monitor the dose received by a worker who breathes or swallows radioactive materials, but it is useful to be able to predict doses that may be received from breathing contaminated atmospheres or swallowing contaminated materials. To make decisions about radiation protection of such workers possible, it is necessary to calculate the amounts of different kinds of radioactive materials which, when breathed in or swallowed, give the maximum dose allowed by the RPGs. Those calculations require complex models of metabolism and dosimetry. We propose that these limiting amounts of radioactivity be designated the "Radioactivity Intake Factors" (RIFs), and that they replace the currently used "Radioactivity Concentration Guides."

Recent advances in modeling metabolism and dosimetry have produced significant changes in the doses calculated for radioactive materials in the body. For many radioactive materials the changes in the RIFs due to changes in the models are considerably larger than the changes due to the proposed new RPGs. These new models more often reduce allowable intakes than raise them. However, for those cases where the RIF for any specific radionuclide would be increased, the question arises whether regulations adopted by implementing agencies should retain existing values, in accordance with proposed Recommendations 2 and 6. We believe that, for existing applications, experience gained over the past two decades shows that current values can be reasonably achieved. Accordingly, in cases where the RIF for any specific radionuclide would be increased under the proposed guidance, we recommend that the value adopted in regulations governing existing applications be no higher than that now in use. A summary of the changes due to the new models and to the proposed new guides is provided for the more significant radionuclides in the background report.

Limitation of Risk From Mutations

The current guides for limiting dose to the gonads are identical to those for the whole body. For a given annual dose, the risk of mutational effects in all of a male worker's descendants combined is believed to be numerically comparable to his lifetime risk of fatal cancer. The risk to a female worker's descendants is smaller. The medical severity of these hereditary effects is usually less than, and, at worst, comparable to, death from cancer. For these reasons we do not believe that a more restrictive guide is required for the gonads than for the whole body. The proposed new guide for gonadal dose is therefore identical to that proposed for the whole body. This guide is specified separately and not included in the scheme proposed above for weighting partial-body doses because the risks involved are of a fundamentally different nature: the affected individual is not the one exposed to radiation and the effects include different types of harm.

Limitation of Risk to the Unborn (Fertilized Oocyte, Embryo, and Fetus

Protection of the unborn from radiation is an already well-established principle; the purpose of the guide for gonadal exposure is to limit mutational effects in children conceived after the exposure. However, those conceived but not yet born, the "unborn," are also at risk. Their risks are greater, for a given dose, than the risks to those not yet conceived. Current guidance does not contain a dose limitation to protect the unborn from these risks.

The risk of serious harm following in utero exposure requires careful attention because of the magnitude and diversity of the effects, because they occur so early in life, and because those who suffer the harm are involuntarily exposed. These risks are not as well quantified as those to adults. Nevertheless, available evidence indicates that at critical periods in the development of the unborn, for the same dose, risks may be many times greater than those to adults.

There are several factors which mitigate this situation. First, the exposure of most workers under annual limits is relatively evenly distributed over the year, so that only a quarter of a worker's annual dose is delivered to the unborn during any trimester. Second, the mother's body provides considerable shielding of the unborn for most types of exposure. Finally, the total period of potential exposure is small for the unborn compared to that for a worker—a period of months compared to a working lifetime.

It is difficult to provide for protection of the unborn without affecting the rights of women to equal job opportunities. This difficulty is compounded because the critical period for most harm to the unborn occurs soon after conception—during the second and third month after conception, when a woman may not know that she is pregnant. Based on our assessments of the risks and the other factors noted above, we believe that the maximum dose to the unborn should be a factor of ten below the maximum permitted adult workers in any year. This is also the current recommendation of the National

Council on Radiation Protection and Measurements. In Recommendation 8 we propose four alternatives which would, with varying degrees of certainty, achieve this objective.

The first two alternatives rely upon voluntary compliance and, therefore, should have less impact on equal job opportunities for women. The first assumes a woman knows she is pregnant within six weeks of conception, and will then, along with her employer, take appropriate protective action. It therefore does not guarantee that doses to the unborn during the critical early stages of pregnancy will be less than 0.5 rem.

The second alternative adds a voluntary limit on dose rate to women who can bear children in order to protect the unborn whose existence is not yet known. It permits women to hold any job, but encourages women able to bear children not to take those few jobs which potentially involve high dose rates.

The third alternative insures protection of all unborn throughout gestation by making the voluntary requirements of the second mandatory. It would bar women of child-bearing capacity from those few jobs which involve high dose rates.

The final alternative would restrict the exposure of all workers, male and female, to a level which would protect the unborn at the level of the first alternative. This alternative preserves equal job opportuntity for women at the cost of causing more total harm. Studies of several high exposure activities show that decreasing the dose limits to this extent would significantly increase the collective dose to workers, and that some current activities would not be possible.

None of these alternatives is completely satisfactory; they each involve either varying degrees of adequacy of protection of the unborn, some sacrifice of equal job opportunity for women, or causing more total harm, or foregoing some of the benefits to society from activities using radiation. We invite public comment on the relative importance to be attached to each of these factors in formulating guidance, and on whether or not the guidance should address this matter now. We would also be happy to receive suggestions for other alternatives.

Limitation of Other Risks

The risk of nonfatal cancer is not only intrinsically less important than that of fatal cancer, but is very much smaller than other nonfatal occupational risks. Thus, we believe the protection provided against fatal cancers includes adequate protection against nonfatal cancers.

While adequate protection against cataracts of the lens of the eye might be provided by a higher maximum average annual dose than the 5 rem now allowed, no operational difficulty is reported with use of 5 rem as an annual limit. That value is therefore retained in these proposals.

The maximum annual dose for skin of the whole body is maintained at 30 rem, since a need for allowing higher doses has not been demonstrated. However, the current guide permits 75 rem to hands and forearms, or feet and ankles, because of the assumed lower risk when only these portions of the skin and underlying tissue of these extremities are involved. We agree that at low dose rates the risk depends in some degree on the amount of skin and tissue exposed, and that exposure of the extremities is therefore less dangerous than of the whole body. However, for forearms, feet, and ankles such a high value is not needed and we propose that the guides for skin and the whole body apply to these extremites. For the hands a higher value appears to be justified for work in glove boxes. It is proposed to be 50 rem, the limit recommended by the ICRP.

Other Considerations

These recommendations apply to workers exposed to other than normal background radiation on the job. It is sometimes hard to identify such workers, because everyone is exposed to natural sources of radiation and many occupational exposures are small. Regulatory agencies will have to use care in selecting classes of workers whose exposure does not need to be regulated. In selecting such classes we recommend that the agency consider both the collective dose which is likely to be avoided through regulation and the maximum individual doses possible.

The question often arises whether or not exposure for medical purposes and other nonoccupational exposures should be considered in calculating the doses that workers receive within the guides. If there were a threshold for risk of health effects from radiation, this could be an important consideration. However, since we assume that the risk at low doses is proportional to the dose, each exposure must be justified on its individual merits. For this reason, in Note 1 to the recommendations we exclude medical and other nonoccupational exposure from the total calculated occupational radiation exposure of workers.

In many jobs diagnostic x-ray examinations are a routine part of periodic or pre-employment physical examinations. Some of these examinations are a condition of employment and some are not. Federal radiation protection guidance on use of diagnostic x-rays was issued by the President on February 1, 1978 (43 FR 4377). These recommendations provide that, in general, use of such x-ray examinations should be avoided unless a medical benefit will result to a worker, considering the importance of the x-ray examination in preventing and diagnosing diseases, the risk from radiation, and the cost. Although all of the recommendations in that guidance may be usefully applied to x-ray examinations of workers, Recommendations 1 through 4 are particularly pertinent. Because this matter has been addressed by separate Federal guidance, exposure from such diagnostic x-ray examinations is not included in this guidance for occupational exposure.

Current Federal guidance provides that occupational doses to minors (those below the age of eighteen) be limited to one tenth the RPGs for older workers. We propose no change.

No other general types of exposed workers are singled out for special protection by these recommendations. However, one special class of workers—underground uranium miners—is already subject to a separate Federal guide (36 FR 12921). That guide limits exposure of their lungs to radioactive decay products of radon gas. The Mine Safety and Health Administration regulates exposure of all underground miners in accordance with this guide. We expect to review the guide on the exposure of miners to decay products of radon in the future. Exposure of miners to other radiation is governed by the Federal radiation protection guidance in these proposed recommendations.

We have not addressed the issues of emergency exposures or of whether overdoses in one year should lead to additional restrictions on doses in future years. Such situations must be dealt with on the merits in each case and under the regulatory mandate of the controlling Federal agency. We do not consider it either practical or reasonable to prejudge or prescribe general conditions for such situations beyond the general principles which apply to all radiation exposure that are set forth below in Recommendations 1 and 2.

We recognize, in addition, that some situations may exist which justify planned exposures exceeding the guides. Recommendation 9 provides for this. It requires that the controlling Federal agency fully consider and disclose the reasons for any such exposures.

Estimated Impact of These Proposals

We estimated above that the exposure of 1.1 million workers in 1975 (the latest year for which we have complete statistics) will lead to 15–36 additional premature cancer deaths and comparable numbers of serious mutational effects and nonlethal cancers. If this new guidance is adopted, workers should be harmed less in the future. We are not able to quantify the improvement because we cannot predict how efficiently the guidance will be implemented and we do not know how much of existing exposure is unjustified. However, the proposed recommendations provide a framework of graded minimum requirements to cut down the amount of unjustified exposure, and a recommendation that implementing agencies establish lower regulatory limits for workers who can operate significantly below the new maximum limits. We believe that most workers can. The proposals also reduce the maximum annual and lifetime dose that any workers can get by about 60%.

We have made only a limited assessment of the costs of implementing this proposed guidance. We do not believe it would be prudent to attempt a detailed analysis, because agencies developing regulations to carry out this guidance may use different means, and their specific proposals will be subjected to public review and economic analysis when they are developed.

The principal cost will be that associated with reduced RPGs. in order to comply with a reduced RPG an enterprise can hire more workers, reassign (and, if necessary, retrain) present employees, improve its procedures or technology, or curtail the activity. In general, a mix of these will be used, depending on the value of the reduced RPG, on the cost of each alternative, and on other factors. Since we do not know what mix will be used, for the purpose of developing rough numberical estimates of the upper bounds of costs we have used a simple model based on the costs for hiring new workers only.

From the distribution of doses found in our national survey of exposures for the year 1975, we computed the total excess collective dose between the old RPG of 3 rem per quarter and the proposed RPG of 5 rem per year. Dividing this excess by the value of the proposed new RPG gives the minimum number of workers that must be hired to absorb this dose. The average labor cost, including overhead, for each additional worker was assumed to be $40,000 per year. This method yields a cost of about $35 million per year. We believe the actual cost of meeting the new RPG will be much less.

We have also attempted to evaluate costs if existing workers now receiving lower doses are retrained to do high-dose jobs instead of hiring new workers. Some workers are very difficult to replace (e.g., medical professionals, such as cardiologists and radiologists; and workers in small enterprises with very limited labor pools). However, we believe that most workers can be relatively easily retrained (e.g., medical technicians and skilled laborers, such as welders and pipe fitters) to handle tasks which cause higher exposures. We estimate that workers that can be reassigned to these jobs would require training varying from a few days to a few months. For these workers, the costs are expected to range from a few percent to a few tens of percent of the annual cost of new hires. In addition, these costs are incurred only once instead of annually, as in the case of new hires. We therefore estimate that the costs based on the above new hires model may be as much as ten times too high, for the first year, and an even greater over-estimate in succeeding years. We welcome comments on the costs of implementing these proposals, on whether or not the costs are reasonable, and why.

Proposed Recommendations

We propose nine recommendations as guidance to Federal agencies in the formulation of Federal radiation protection standards for workers, and in their establishment of programs of cooperation with States. In all cases but one we have made single recommendations for public comment. The exception, Recommendation 8, addresses protection of the unborn during gestation. Because this recommendation involves issues that go beyond simple radiation protection of workers, including equality of employment rights and the rights of the unborn, we have proposed four alternatives for public consideration. The recommendations follow:

1. All occupational exposure should be justified by the net benefit of the activity causing the exposure. The justification should include comparable consideration of alternatives not requiring radiation exposure.

2. For any justified activity a sustained effort should be made to assure that the collective dose is as low as is reasonably achievable.

3. The radiation dose to individuals should conform to the numerical Radiation Protection Guides (RPGs) specified below. Individual doses should be maintained as far below these RPGs as is reasonably achievable and consistent with Recommendation 2.

Radiation Protection Guides

a. The sum of the annual dose equivalent [6] from external exposure and the annual committed dose equivalent [7] from internal exposure should not exceed the following values:

Whole body—5 rem
Gonads—5 rem
Lens of eye—5 rem
Hands—50 rem
Any other organ—30 rem

b. Non-uniform exposure of the body should also satisfy the condition on the weighted sum of annual dose equivalents and committed dose equivalents, H_w, that

$$H_w = \Sigma_i w_i H_i < 5\text{rm},$$

where w_i is a weighting factor, H_i is the annual dose equivalent and committed dose equivalent to organ $_i$, and the sum excludes the gonads, lens of eye, and hands. Recommended values of w_i are:

Breast—0.20
Lung—0.16
Red bone marrow—0.16
Thyroid—0.04
Bone surfaces—0.03
Skin—0.01
Other organs [8]—0.08

c. When both uniform whole-body exposure and nonuniform exposure of the body occur, in addition to the requirements of 3a, the annual uniform whole-body dose equivalent added to the sum of weighted annual dose equivalents from additional nonuniform exposure, H_w, should not exceed 5 rem.

4. The following Minimum Radiation Protection Requirements should be established by appropriate authorities and carried out in the workplace, on the basis of the range of doses anticipated in individual work situations. The numerical values specifying the dose ranges may be adjusted to fit the needs of specific situations by implementing agencies. [9]

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[6] "Dose equivalent" means the quantity expressed by the unit "rem," as defined by the International Commission on Radiation Units (IU73).

[7] "Annual committed dose equivalent" applies only to dose equivalents from radionuclides inside the body. It means the sum of all dose equivalents that may accumulate over an individual's remaining lifetime (usually taken as 50 years) from radioactivity that is taken into the body in a given year.

[8] Applies only to each of the five other organs with highest doses.

[9] Suggested numerical ranges are: Range A, less than 0.1 RPG; Range B, 0.1–0.3 RPG; Range C, 0.3–1.0 RPG.

Minimum Radiation Protection Requirements

Range A

a. Determine that exposures result only from justified activities and are as low as is reasonably achievable. These determinations may often be made on a generic basis, that is, by considering groups of similar work situations and protective measures.

b. Monitor or otherwise determine individual or area exposure rates to the extent necessary to give reasonable assurance that doses are within the range and are as low as is reasonably achievable.

c. Instruct workers on basic hazards of radiation and radiation protection principles, and on the levels of risk from radiation and appropriate radiation protection practices for their specific work situations. The degree of instruction appropriate will depend on the potential exposure involved.

Range B

The above requirements, plus:

d. Provide professional radiation protection supervision in the work place sufficient to assure that both individual and collective exposures are justified and are as low as is reasonably achievable.

e. Provide individual monitoring and recordkeeping.

Range C

The above requirements, plus:

f. Justify the need for work situations which are expected to make a significant contribution to exposure in Range C and provide professional radiation protection supervision before and while such jobs are undertaken to assure that collective and individual exposures are as low as is reasonably achievable.

g. Carry out sufficient additional monitoring of workers to achieve Recommendation 4f.

h. Once a worker has been exposed in Range C, maintain a lifetime dose record, including at least all subsequent annual doses (as specified in Recommendation 3c) in Ranges B and C.

i. Maintain lifetime doses as low as is reasonably achievable. The accumulation of doses (as recorded under Recommendation 4h) by individual workers should be managed so that their lifetime accumulated dose is less than 100 rem.

5. a. "Radioactivity Intake Factors" (RIFs) should be used to regulate occupational radiation hazards from breathing, swallowing, or immersion in media containing radionuclides. The RIF for a radionuclide is defined as the maximum annual intake (in curies) for which the committed dose equivalent to a reference person satisfies the Radiation Protection Guides in Recommendation 3. RIFs may be derived for different chemical or physical forms, and for intake by breathing, swallowing, or for external exposure from air containing a radioactive gas. Exposure regulated through use of the RIFs should meet the same Minimum Radiation Protection Requirements as equivalent exposure under the Radiation Protection Guides.

b. When a RIF for a specific radionuclide in a specific chemical or physical form determined on the basis of part (a) is larger than that currently in use, a value no greater than that in current use should be adopted in regulations governing work situations identical or similar to those currently in existence.

6. Federal agencies should establish limits and administrative levels that are below the RPGs and the RIFs, when this is appropriate. Such limits or levels may apply to specific categories of workers or work situations.

7. In addition to any other Federal restrictions, the occupational exposure of individuals younger than eighteen should be limited to one tenth of the Radiation Protection Guides for adult workers.

8. Exposure of the unborn [10] should be restricted more than that of workers. This should include special consideration of ALARA practices for women. Women able to bear children should be fully informed of current knowledge of risks to the unborn from radiation. In addition, employers should assure that protection of the unborn is achieved without loss of job security or economic penalty to women workers. Due to the complexity of the issues involved, we propose four alternative recommendations on numerical limitation of dose to the unborn for public comment. We would be glad to receive other recommendations for dealing with exposure of the unborn.

a. Women are encouraged to voluntarily keep total dose to any unborn less than 0.5 rem during any known or suspected pregnancy; or

b. Women able to bear children are encouraged to voluntarily avoid job situations involving whole-body dose rates greater than 0.2 rem per month, and to keep total dose to the unborn less than 0.5 rem during any known pregnancy; or

c. Women able to bear children should be limited to job situations involving whole-body dose rates less than 0.2 rem per month. Total dose to the unborn during any known period of pregnancy should be limited to 0.5 rem; or

d. The whole-body dose to both male and female workers should not exceed 0.5 rem during any six month period.

9. In exceptional circumstances the RPGs may be exceeded, for cause, but only if the Federal agency having jurisdiction carefully considers the specific reasons for doing so, and publicly discloses them unless this would compromise national security.

The following notes clarify application of the above recommendations:

1. Occupational exposure of workers does not include that due to (a) normal background radiation and (b) exposure as a patient of practitioners of the healing arts.

2. When the uniform external whole-body exposure occurs in addition to exposure from radioactive materials taken into the body, the requirement of Recommendation 3c may be satisfied by the condition that

$$\frac{H_{ext}}{RPG_{wb}} + \sum_j \frac{I_j}{RIF_j} \leq 1,$$

where H_{ext} is the annual external whole-body dose equivalent, RPG_{wb} is 5 rem, I_j is the intake of radionuclide j, and RIF_j is defined as in Recommendation 5.

3. The values currently specified by the ICRP for quality factors and dosimetric conventions for measurement of the various types of radiation may be used for determining conformance with the RPGs. The model for a reference person and the metabolic models currently specified by the ICRP may be used to calculate the RIFs. We will recommend other factors, conventions, and models when and if they are more appropriate.

4. Numerical guides for emergency exposures are not provided by this guidance. Agencies should follow the general principles established by Recommendations 1, 2, 7, 8, and 9 in dealing with such situations.

5. Procedures for handling overexposures are not addressed by this guidance. The equitable handling of such cases is the responsibility of the employer and the Federal agency having regulatory jurisdiction.

6. Limits for periods other than one year may be derived by Federal agencies from the annual RPGs and RIFs when necessary for administrative

[10] "Unborn" here means the fertilized oocyte, the embryo, and the fetus.

purposes. Such limits should be consistent with Recommendation 2 and the three ranges in Recommendation 4.

7. The existing guide for limiting exposure of underground uranium miners to radon decay products is not changed by these recommendations.

These proposed recommendations would provide general guidance for the radiation protection of workers. They would replace that part of existing guidance (see 25 FR 4402 of May 18, 1960) which applies to workers. Individual Federal agencies, with their knowledge of specific worker exposure situations, would use this guidance as the basis upon which to develop detailed standards and regulations to meet their particular statutory obligations. We propose to follow the activities of the Federal agencies as they implement the final Guidance, to issue any necessary clarifications and interpretations, and to promote the coordination necessary for an effective Federal program of worker protection.

Public Hearings

Public hearings on these proposed recommendations will be held as indicated above under the heading "Dates." Because of their major responsibilities to regulate radiation exposures in work places, the Nuclear Regulatory Commission (NRC) and the Occupational Safety and Health Administration (OSHA) will participate in sponsoring these hearings. The following conditions and procedures will govern the conduct of the hearings:

1. Purpose, Type, and Scope

These hearings are to provide additional opportunity for people to express opinions and provide factual information to aid EPA, OSHA, and NRC in carrying out their respective responsibilities for guidance on and regulation of occupational exposure to ionizing radiation. The hearings will be informal and legislative in nature rather than adjudicatory or formal rulemaking hearings. Technical rules of evidence, discovery, subpoena powers, testimony under oath, and similar formalities will not apply.

The issues to be covered by these hearings are those listed above under the heading "*Issues Addressed.*" They include those listed in our advance notice of September 17, 1979 (44 FR 53785) and additional issues suggested since then. As indicated in that notice, both EPA and NRC have been petitioned by the Natural Resources Defense Council, Inc., to revise occupational guidance and standards. The subject matter of these hearings encompasses the issues raised in those petitions (See 40 FR 50327 of October 29, 1975).

2. Presiding Officer and Panel

The hearings will be conducted by a presiding officer. A six member panel consisting of representatives of EPA, OSHA, and NRC will assist the presiding officer. A principal responsibility of the panel will be to clarify the testimony by eliciting views, comments, and factual information from participants. Members of the panel will not present views or respond to questions on behalf of their agencies. The membership of the panel may vary from time to time.

The presiding officer and panel shall have the joint responsibility to assure a fair and impartial hearing and to encourage the development of testimony that will contribute to informed decision-making. It will not be the function of the presiding officer or the panel to issue an opinion or to make decisions at the conclusion of the hearings. The presiding officer shall conduct the hearings in an orderly, fair, and expeditious manner and make procedural decisions. His functions shall include, but not be limited to, the following:

a. Regulating the course of the hearings and the conduct of participants, including establishing reasonable time limits for the hearings, establishing the sequence and length of presentations and questioning, and opening and closing each hearing session;

b. Making determinations concerning procedure and similar matters;

c. Assuring that questioning of speakers by panel members and others is consistent with the nature and purpose of these hearings;

d. Making determinations on the relevance of oral testimony and questions to the issues identified as within the scope of the hearings, or, in consulation with the panel, to additional issues pertinent to the proceedings; and, as necessary, terminating irrelevant presentations;

e. Ruling on late requests to participate;

f. Deciding how long the hearing record will remain open for written comments and additional data after the end of the oral proceedings.

3. Participation in the Hearings

Persons or organizations who wish to give presentations longer than ten minutes or present extensive data and evidence must give written notice to the Director, Criteria and Standards Division (ANR-460), U.S. Environmental Protection Agency, Washington, D.C. 20460, no later than 28 days prior to the scheduled date of a hearing. The notice should include: (1) the name, address, and telephone number of the participant; (2) the hearing at which they wish to testify; (3) the organization (if any) that they will represent; (4) the amount of time requested; and (5) which of the issues they want to address. Oral presentations will generally be restricted to 30 minutes. Detailed or lengthy material should be summarized orally and presented in full in written submissions. Requests for longer times for oral presentations will be condsidered only on the basis of a detailed summary of the material to be presented. The Agency will notify participants in advance if their allocated time is less than that requested.

An opportunity will be provided each day of the hearings for persons who have not submitted a notice as specified above to make brief oral statements. A register will be provided at the beginning of each hearing for this purpose. A minimum period will be set aside for such statements in the agenda for each hearing, and the presiding officer may allocate additional time, as necessary. The maximum time allowed for such statements will depend on the number of registrants and the availability of time, but will generally be limited to periods of no more than 5 to 10 minutes each. In order to assist the management of the hearings, persons wishing to make such statements are encouraged to register promptly at the beginning of the hearing.

Attendance at the hearings will be open to all members of the public, and seating will be made available on a first-come first-served basis.

4. Testimony and Written Submission

a. The oral proceedings will be recorded verbatim and a transcript made availabe promply for inspection and copying, as specified below under the heading "The Public Hearing Record." It will help the panel if speakers supply copies of their oral testimony before they give it. However, this in not required.

b. Fourteen copies of any written statements and documents on which speakers intend to base their oral statements must be submitted to the Director (see "Addresses" above) no later than 14 days before the beginning of the hearing in which they will testify. We would appreciate if speakers would also provide eight additional copies for the use of the panel.

c. Questions may be directed to speakers by the hearing panel, by other speakers, and by other members of the public. Speakers may respond or not, as

they wish. Questions should be designed to elicit relevant information and should not be repetitious of questions asked by others. The views of questioners should be expressed in their statements and not as prefaces to questions. Such informal questioning will be at the discretion and under the control of the presiding officer.

d. Members of the public who are not able to attend the hearings or prefer not to ask questions themselves may suggest questions to the hearing panel to ask of speakers. These must be submitted no later than 14 days before any hearing to the Director (see "Addresses" above). The panel will decide whether or not to ask these questions.

e. Members of the public may also submit comments during the post-hearing comment period set by the presiding officer. These post-hearing comments should be confined to responses to data and opinions submitted at the hearings or to written comments received by the Agency.

f. In addition to these public hearings, we would appreciate any written comments on these proposals. These will be given equal consideration in formulating final recommendations. The procedure for submitting such written comment is given above under the headings "Dates" and "Addresses." Participants in the hearings may refer to and comment on such written comments, which will be available for public inspection and copying as specified below under "The Public Hearing Record."

5. Opening Statement

At the opening of each hearing, EPA will provide a summary statement of the proposed recommendations and of the major issues involved. At that time speakers and other members of the public can ask questions of the EPA representatives in order to clarify the proposed recommendations and the reasons why EPA is proposing them.

6. The Public Hearing Record

The procedures for filing documents in these hearings will be specified by the presiding officer, except as already provided herein.

The hearing record will include the transcript of oral statements by speakers, the questions and answers, and all written materials filed in connection with these hearings. Items in this public hearing record will be filed under EPA Docket No. A–79–46 and will be available for public inspection and copying as soon as possible following their receipt, at the U.S. Environmental Protection Agency's Central Docket Section, Room 2903B, Mall, 401 M Street, S.W., Washington, D.C. 20460, and at each of the Agency's ten regional offices (see "Addresses" above).

Dated: January 16, 1981.

Douglas M. Costle,

Administrator.

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